REMARKS

In the Official Action dated May 5, 2004, claims 33, 36, and 39-62 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling disclosure.

This Response addresses the Examiner's rejection under 35 U.S.C. §112, first paragraph. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is, therefore, respectfully requested.

Claims 33, 36, and 39-62 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling disclosure. For the reasons that follow, Applicants respectfully traverse this rejection and request that it be withdrawn.

Applicants respectfully submit that the specification of this case contains support sufficient to enable those skilled in the art to practice the invention as claimed in claims 33, 36, and 39-62. The pharmaceutically active compounds employed in these claims are described on pages 2-13 of the specification, and methods by which such compounds can be prepared are described in detail on pages 18-29 of the specification. A description of how the foregoing claimed pharmaceutical compositions can be prepared appears on pages 28-32 of the specification. All of the descriptions in the specification that are referred to above are written in clear and concise language using terms that are familiar to those skilled in the art.

Moreover, the specification sets forth in detail, on pages 31-35, how the methods of claims 36 and 39-62 can be carried out by those skilled in the art. It specifies, on these pages, not only the conditions that can be treated or prevented by the administration of a pharmaceutical composition according to claim 33, but also

appropriate dosages and methods of administration. This description includes the various modes by which the compounds employed in the claimed methods can be administered to mammals, the pharmaceutically acceptable forms in which they can be administered, and appropriate dosages for their administration. The foregoing information is sufficient to enable one skilled in the art to practice the inventions of each of the pending claims, and thus complies with the requirements of 35 U.S.C. §112.

Applicants respectfully submit that a specification disclosure that contains a teaching of the manner and process of making and using the invention in terms that correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112, unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. In re Marzocchi, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Further, the burden is on the Examiner to come forth with evidence to establish a prima facie case of non-enablement. Ex parte Hitzeman, 9 U.S.P.Q. 2d 1801, 1822 (Pat. Off. Bd. App. 1988); In Re Armbruster, 185 U.S.P.Q. 152, 153 (C.C.P.A. 1975); In re Marzocchi, 169 U.S.P.Q. at 370.

Applicants respectfully submit that the Examiner has not proffered any evidence that would cause one skilled in the art to doubt the objective truth of the enabling support set forth in the present specification.

Applicants respectfully submit that they are not required under the first paragraph of 35 U.S.C. §112 to provide chemical or biological data or to otherwise "substantiate that their claimed compounds and compositions are useful in treating the various disorders and conditions named in the rejected claims. This paragraph requires

only that Applicants provide a description of each claimed invention, in clear and concise terms, that is sufficient to enable those of skill in the art to practice each such invention, including what they contemplate to be the best mode of practicing each such invention. As explained in detail above, Applicants have satisfied this requirement.

Applicants respectfully submit that one of skill in the art would not need data to practice the inventions of claims 33 and 39-62. The specification teaches that all the compounds employed in the pharmaceutical compositions and methods of these claims are substance P receptor antagonists and that they are useful in treating the various named disorders and conditions. The Examiner has not proffered any evidence to show that those skilled in the art would doubt the objective truth of these statements. Therefore, such statements must, as indicated above, be accepted as true.

Applicants also respectfully submit that experimental examples are not required to support the complete scope of a claim. Working examples are not a necessary part of a patent application. Neither the patent laws nor the U.S.P.T.O. Rules of Practice require that a patent application contain any working examples of a claimed invention. It is contrary to the original intent of the Patent Laws in this country to require an applicant to limit the claims to materials disclosed in the examples. "To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts." In re Goffe, 191 U.S.P.Q. 429, 431 (C.C.P.A. 1976).

The number and variety of examples are irrelevant if the disclosure of the patent application is enabling and sets forth the best mode contemplated. In re

Borkowski, 164 U.S.P.Q. 642, 646 (C.C.P.A. 1970).

Applicants have submitted an enabling disclosure, including what they believe to be the best mode for making all the compounds claimed in this application. They have therefore complied with the statutory requirements of 35 U.S.C. §112.

Applicants, therefore, submit that all pending claims comply fully with the provisions of 35 U.S.C. §112 and respectfully request that the Examiner withdraw the foregoing rejection under this section.

The Examiner's requirement that Applicants "substantiate treating and preventing all of the alleged diseases...", in view of the extensive enabling description in the specification, while stated as grounds for a 35 U.S.C. §112 rejection, goes to the issue of utility rather than enablement. Applicants have, therefore, addressed this issue below.

Applicants respectfully submit that the utility of all the claimed inventions in this application is both clearly stated in the specification and credible to those skilled in the art, and that all pending claims therefore meet the requirement of patentable utility under 35 U.S.C. §101.

The specification clearly sets forth, on page 31, the utilities of the claimed pharmaceutical composition and methods of claims 33 and 36-62. A specification that contains a disclosure of utility that corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of 35 U.S.C. §101 for the entire claimed subject matter unless there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope. In re Lancrer, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974). While proof of such utilities has not been provided, such utilities are not unbelievable or incredible on their face.

The present application is easily distinguishable from those applications for which the asserted utility was held to be so incredible as to require objective proof. In Ex Parte Heicklen, 16 U.S.P.Q. 2d 1463, the Board of Patent Appeals and Interferences held that the asserted utility of the claimed compounds, retardation of the aging process, was so incredible as to require objective proof. Similarly, in In re Newman, 228 U.S.P.Q. 451 (Fed. Cir. 1986), the Federal Circuit affirmed the district court's order that the patent applicant produce for testing his claimed "energy generating system" that was alleged to have a higher energy output than input.

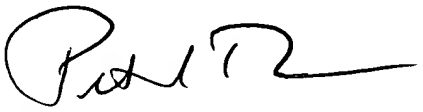
In sharp contrast to a machine that allegedly outputs more energy than it inputs and to a drug that allegedly retards the aging process, there is nothing incredible about the claims of the present case. Therefore, Applicants respectfully submit that there is no legal obligation to provide proof of utility.

In view of the fact that the Examiner has proffered no evidence that the asserted utilities of Applicants' claimed pharmaceutical compositions and methods of treatment are "wholly without scientific basis" or "not consistent with the evidence of record and current scientific knowledge", Applicants respectfully submit that they are not required to provide chemical or biological data in support of the rejected claims.

Applicants further submit that, in view of the above facts and legal precedents, all pending claims are patentable and respectfully request that they be allowed to issue.

Thus, in view of the foregoing amendments and remarks, the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

PIB/RLB:nis/gc